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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,920	12/28/2006	Philip J. Simpson	ICUMM.376A	1318

20995 7590 06/29/2009

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EXAMINER	
BOSWORTH, KAMI A	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
06/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,920	SIMPSON ET AL.	
	Examiner	Art Unit	
	KAMI A. BOSWORTH	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-10 and 31-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-10 and 31-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment received 6/11/2009. As per the amendment, claims 1, 2, and 6-10 have been amended, claims 3-5 and 11-30 have been cancelled, and new claims 31-42 have been added. Therefore, claims 1, 2, 6-10, and 31-42 are presently pending.

Response to Arguments

2. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 6-10, and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (PG PUB 2003/0136932) in view of Paradis (US Pat 6,063,062).

5. Re claim 1, Doyle discloses a valved male luer medical connector (Fig 11) comprising: a male luer end portion 55 (Fig 11) in a distal side of the connector, the male luer portion comprising interior and exterior surfaces and a bore extending

between the interior and exterior surfaces (as seen in Fig 11); a female luer end portion (as seen in Fig 11) in a proximal side of the connector and a channel (defined within valve portions 54 and 56, Fig 11) for the transfer of fluids between the male and female luer end portions (Para 41); a valve member 54,56 (Fig 11) movable between a closed position (as seen in Fig 11) and an open position (as seen in Fig 12), the valve member comprising a first proximal portion 54 (Fig 11) and a second portion 56 (Fig 11) distal from the first portion, the second portion being positioned at least partially within the male luer portion in the closed position (as seen in Fig 11) and generally enclosing inside of the second portion a first generally longitudinal fluid pathway (Para 41), the valve member further comprising a plug portion (formed near end 58, Fig 11) distal from the second portion, the plug portion being closed-ended in both the open and closed positions (as the plug is one solid piece), and the plug portion being configured to engage the interior surface of the male luer portion to form a seal such that the closed end of the plug portion is generally flush with a distal end of the exterior surface of the male luer portion in the closed position (as seen in Fig 11; Para 41); a seal 132 (Fig 14) extending generally around a portion of the second portion of the valve member; a biasing member 68 (Fig 11) configured to bias the valve means member toward the closed position, at least a portion of the biasing member generally surrounding at least a portion of the first proximal portion of the valve member, the biasing member being separate from the seal (as seen in Fig 11); and an actuating member 60 (Fig 11) extending distally into a region near the exterior surface of the male luer end portion in the closed position, the actuating member being coupled to the valve member (via

extending member 65, Fig 11), and the actuating member being configured to actuate the valve member from the closed to the open position when a female luer end portion of a medical accessory is advanced into the distal side of the connector (as seen in Fig 12; Para 41), wherein the actuating member, the first proximal portion of the valve member, and the second portion of the valve member are configured to be non-deformable upon contact with the female luer end portion of the medical accessory (as seen in Fig 12). Doyle does not disclose a second generally transverse fluid pathway in fluid communication with the first. Paradis, however, teaches a substantially similar valve 12 (Fig 1A) generally enclosing a first generally longitudinal fluid pathway 13-s (Fig 1A) and a second generally transverse fluid pathway 12-1,12-2 (Fig 1A) in fluid communication with the first (as seen in Fig 1C) for the purpose of guarding against back pressure through the valve (Col 6, Lines 30-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Doyle to include a second generally transverse fluid pathway, as taught by Paradis, for the purpose of guarding against back pressure through the valve (Col 6, Lines 30-45).

6. Re claim 2, Doyle discloses that the distal side of the connector comprises an outer threaded sheath 52 (Fig 11), the actuating member including a portion positioned between the outer threaded sheath and the male luer portion (as seen in Fig 11).

7. Re claim 6, Doyle discloses that the valve member is integrally formed with the female luer end portion (as seen in Fig 11; Para 39).

8. Re claim 7, Doyle discloses a housing portion 52 (Fig 11), wherein the valve member includes an anchor flange 65 (Fig 11) extending outwardly toward an inner surface of the housing portion (as seen in Fig 11).

9. Re claim 8, Doyle discloses that the housing portion is coupled to the male luer end portion for movement therewith relative to the valve member (via support 53, Fig 11; Para 39).

10. Re claim 9, Doyle discloses that the male luer end portion engages the anchor flange when the valve member is in the closed position and the male luer end portion is spaced from said anchor flange when the valve member is in the open position (as seen in Fig 11; Para 41).

11. Re claim 10, Doyle discloses that the housing portion terminates at an end region adjacent the female luer end portion (as seen in Fig 11), the biasing member includes a compression spring 68 (Fig 11) located within the housing portion between the end region and the outer anchor flange.

12. Re claim 31, Doyle discloses that the valve member further comprises a radially extending member 65 (Fig 11) forming a transition between the first and second portions of the valve member (as seen in Fig 11).

13. Re claim 32, Doyle discloses that the biasing member is a compression spring 68 (Fig 11).

14. Re claim 33, Doyle discloses that the biasing member does not contact the actuating member or the second portion of the valve member (as seen in Fig 11).

15. Re claim 34, Doyle discloses that the biasing member is contained entirely within an interior region of the connector (as seen in Fig 11).

16. Re claim 35, Doyle discloses that the plug portion has a distal end that is narrower than any portion of the second portion of the valve member (best seen in Fig 12).

17. Re claim 36, Doyle discloses that the distal end of the plug portion is narrower than any other portion of the valve member (best seen in Fig 12).

18. Re claim 37, Doyle discloses that the seal is stationary when the valve member moves (in relation to the valve (as seen between Fig 11 and Fig 12).

19. Re claim 38, Doyle discloses that the plug is non- deformable in the open and closed positions (Para 39-41).

20. Re claim 39, Doyle discloses all the claimed features except a second generally transverse fluid channel consisting of side openings. Paradis, however, teaches a substantially similar valve 12 (Fig 1A) generally enclosing a first generally longitudinal fluid pathway 13-s (Fig 1A) and a second generally transverse fluid pathway that consists of side openings 12-1,12-2 (Fig 1A) on opposing sides of the valve member (as seen in Fig 1A) for the purpose of guarding against back pressure through the valve (Col 6, Lines 30-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Doyle to include a second generally transverse fluid pathway with side openings, as taught by Paradis, for the purpose of guarding against back pressure through the valve (Col 6, Lines 30-45).

21. Re claim 40, Doyle discloses an outer housing 52,53 (Fig 11) made of two discrete parts coupled together (Para 39).

22. Re claim 41, Doyle discloses a second seal 132 (Fig 14) positioned near the first proximal portion of the valve member (as seen in Fig 11).

23. Re claim 42, Doyle discloses that the first proximal portion generally encloses a fluid channel positioned inside the first proximal portion (Para 41).

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is

(571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767